

June 12, 2018

VIA FEDEX

DEFENSE LOGISTICS AGENCY
Andrew T. McNamara Building
8725 John J. Kingman Road
Fort Belvoir, VA 22060-6221

Re: Freedom of Information Act Request re: Lariam and Mefloquine

Dear Sir/Madam:

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552 et seq. ("FOIA"), we hereby respectfully request on behalf of the public any and all records relating to the use of the prescription drug Lariam (as defined below) by the U.S. Department of Defense and all U.S. military service members and relating to the procurement of Lariam from F. Hoffmann-La Roche pharmaceuticals and any of its affiliates since 1989.

For purposes of this request:

- "Lariam" means the prescription drug sold under the brand name Lariam or its generic name mefloquine.
- "Roche" means F. Hoffmann-La Roche, Ltd. and the group of global companies that are affiliated with F. Hoffmann-La Roche, Ltd.. Some of the companies affiliated with F. Hoffmann-La Roche, Ltd. include F. Hoffmann-La Roche, Inc., Genentech, and Roche Biomedical Laboratories, Inc.
- "Records" has the same meaning as defined in FOIA, including any and all materials, documents, records, letters, correspondence, e-mails, complaints, criminal or civil actions, findings, results, statements, reports, investigations (completed or otherwise), inquiries, hearings, proceedings, studies, testimony, or other information, whether stored in hard copy or electronically.
- "Relating to" shall be interpreted as expansively and liberally as possible and shall include pertaining to, involving, concerning, referencing, regarding, mentioning, acknowledging, revealing, discussing, having anything to do with or about.
- "Persons" means any individual, a partnership, a corporation, a limited liability company, an association, a joint stock company, a trust, a joint venture, an

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unincorporated organization or any foreign or domestic governmental authority, including any federal, provincial, state, territorial or municipal government, and any government agency, court, tribunal, commission or other instrumentality or authority exercising or purporting to exercise executive, legislative, judicial, regulatory or administrative functions of, or pertaining to, government, and any official of any of the foregoing.

Specifically, we respectfully request access to, and a copy of, all Records relating to the following matters:

1. All Records relating to policies, practices, rules, regulations, guidance, warnings, and memoranda regarding the procurement, distribution, and prescription of Lariam to U.S. service members domestic and abroad.
2. All Records relating to policies, practices, rules, regulations, guidance, warnings, and memoranda regarding the assessment of U.S. service members prior to the distribution of Lariam to U.S. service members and assessments subsequent to the distribution of Lariam to U.S. service members.
3. All Records relating to the solicitation, procurement, distribution, delivery, and acceptance of Lariam from Roche or any other manufacturer or distributor of Lariam, including all requests for proposals, requests for qualifications, solicitation documents, negotiations, invoices, bills, and any other Record related to the transfer of Lariam pills to and within the U.S. Department of Defense.
4. All Records relating to the manufacturers, distributors, and wholesalers of Lariam.
5. All Records relating to Roche.
6. All Records relating to adverse effects of Lariam among all personnel of U.S. Department of Defense, including all U.S. service members.
7. All Records relating to any correspondence and communication between the U.S. Department of Defense and the Food and Drug Administration regarding Lariam.
8. All Records relating to Lariam.
9. All Records relating to the policies, practices, rules, regulations, guidance, warnings, and memoranda regarding the manner in which the U.S. Department of Defense determines the type of prescription drug used for malaria prevention and treatment.

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10. All Records relating to the prevention and treatment of malaria by the U.S. Department of Defense.

11. All Records relating to medical or scientific studies or literature relating to Lariam.

12. All Records relating to the potential hazards, safety concerns, or side effects of the use of Lariam by U.S. Department of Defense personnel.

13. All Records relating to any research, studies, or monitoring of the potential hazards, safety concerns, or side effects of the use of Lariam by U.S. Department of Defense personnel.

14. All Records that have ever been requested from Roche, that have ever been provided to Roche, that have ever been requested from Roche, or that have ever been provided by Roche.

15. All Records that have been requested by, provided to, requested from, or provided by:

A. Any experts, consultants, or private interests;

B. All other federal and state governmental entities, including the National Institute of Health or any component thereof, The Center for Medicare and Medicaid Services (formerly known as the Health Care Finance Administration), the Department of Veterans Affairs, the Public Health Service, the Centers for Disease Control and Prevention, Department of Health and Human Services or any component thereof, any member of the Congress of the United States or their representatives, and other state or federal departments, agencies, governments, or political subdivisions;

C. All other public and private health care entities, including, but not limited to, any health care insurers, managed care organizations, public or private formularies, boards of medicine or boards of pharmacy, and pharmacy benefit management companies;

D. All foreign governments, or agencies thereof (including any military agencies or departments), including, but not limited to, the European Union Committee for Proprietary Medicinal Products (CPMP), the United Kingdom's Medicines Control Agency (MCA), France, Canada, Ireland, Australia; and

E. All Office of the Attorney General, District Attorney or other prosecutorial, investigative or law enforcement-type federal, state, local or foreign agencies.

16. All Records relating to the incident involving the homicide of the wives of four U.S. service members at Ft. Bragg in or around 2002.

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17. All Records relating to any studies, reports, research, or investigation of suicidal or homicidal ideations of U.S. service members, suicides of U.S. service members, homicides by U.S. service members, or permanent neuropsychiatric symptoms or conditions, in each case that is caused by or linked to Lariam.

This requests includes, but is not limited to copies of all information, materials, documents, e-mails, electronically stored information, disks, compact disks, electronic files, tapes (audio, video, and digital), and any other information relating to the above items, regardless of the format or medium in which the information is stored. To the extent possible, we would request that the information be produced to us in an electronic format.

We respectfully request that any fee for this service be waived, in the interest of public health and safety. This waiver could potentially allow for those persons harmed or injured by Lariam to obtain proper medical care and treatment. We agree to pay the reasonable cost of duplication and certification, up to five thousand dollars (\$5,000) to the extent fees are not waived. Please contact us if costs will exceed this amount.

If you refuse to produce any information requested, please advise us in writing, and indicate the specific reason(s) or exemption(s) upon which such denial is based. If the denial only applies to a portion of the material, please "black-out" or redact only that portion, and produce the redacted version of the document. By making this request, we do not waive our right to appeal any decision denying our requests for information, denying a fee waiver, or denying expedited review or to file an action in a federal district court to enforce these FOIA requests.

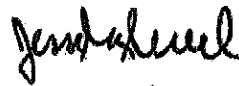
Please provide expedited review because delayed disclosure could threaten the life or health and safety of persons exposed to Lariam. The expedited release of the requested information could potentially allow such persons to obtain remedies involving medical monitoring and appropriate medical care. I certify that these statements regarding expedited review are true and correct to the best of my knowledge and belief.

We respectfully request you comply with this request within twenty (20) days as provided by the statute. Please certify the documents as public records pursuant to Federal Rule of Civil Procedure 44 and Federal Rule of Evidence 902. Please produce the requested materials to us at the below address, via Federal Express, which may be billed to our account number 316524982.

Please contact us if there are any questions or concerns relating to this request so that we may assist you in the expedited production of the materials requested. Thank you for your prompt attention to this matter.

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Sincerely,

A handwritten signature in black ink, appearing to read "Jesse Max Creed". The signature is written in a cursive, slightly slanted style.

Jesse Max Creed

JMC

